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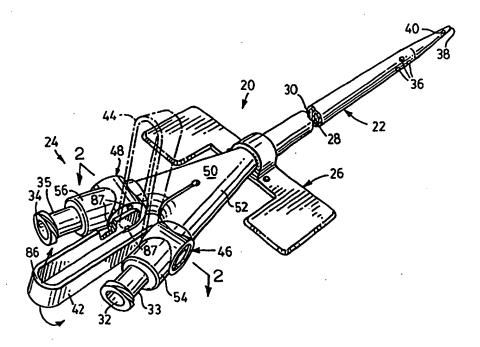
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(54) Title: CATHETER HAVING GANGED ROTARY VALVES



(57) Abstract

The invention provides a catheter comprising an elongate main body including a pair of lumens and extending between proximal and distal ends and connection structure including a housing attached directly to said proximal end and defining a pair of passages forming continuations of the respective lumens, a pair of rotary valves including valve housings formed in said housing and having respective axes of rotation lying in a common plane and including barrels rotatable in said valve housings on actuation of the valves, and a ganged operator attached to the barrels between the barrels for actuating the valves.

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DESCRIPTION

CATHETER HAVING GANGED ROTARY VALVES TECHNICAL FIELD

This application relates to catheters having two lumens and used in procedures requiring intrusion into the blood circulation system of a patient, and normally referred to as vascular access catheters. More particularly, the invention relates to such catheters having a connection structure at the proximal end including a pair of rotary valves operable to control flow through the lumens.

BACKGROUND ART

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Vascular access catheters have been developed as single lumen, dual lumen or multi-lumen catheters and are used for a variety of procedures, all of which involve intrusion into the blood circulatory system. The main body of the catheter is designed for this intrusion and the proximal or outer end includes extensions, one for each lumen. It is common practice to make these extensions from flexible tubing with each of the tubes fitted with a luer lock connector at its free end for attachment to fluid lines, and also for closing and sealing the lumens when the catheter is not in use. Because these connectors may fail, it is also common practice to place a clamp about each of the extensions so that this can be used to close the extension if needed.

This second line of defence is made necessary because it is possible that the luer lock and its cap may fail due to misuse or to simple flaws created during manufacture. It is evident that should the lines of defence fail while the catheter is in place, the patient is at risk of bleeding to death or suffering an air embolism if the failure is not detected very quickly.

Flexible tubes and clamps are not entirely satisfactory.

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The most serious problem is that the clamps close the tubes by a pinching action and if the clamp is in place for a significant length of time, it is not uncommon that the tubing will not recover when the clamp is released. The resulting crease in the tubing causes flow problems and in extreme cases the catheter has to be removed because the tube is no longer patent. The problem is most prevalent on catheters that have thermoplastic tubular extensions made from or polyurethane (PU). Also the problem is exacerbated by the fact that the extensions are attacked in a mild way by organic solvents such as alcohol that is always present in heparin, the anti-coagulant drug of choice used in catheters to maintain the patency of the catheter when not in use.

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An alternative to PU is silicone rubber which is not attacked by solvents such as alcohol. Consequently the walls will not stick to one another, and this combined with the good rebound properties, make it suitable for use as extension tubes. Although some manufacturers use silicone rubber extensions for this reason, there is a secondary problem which has resulted in silicone rubber being superseded by PU. The problem relates to the fact that silicone is not thermoplastic and does not bond readily. Consequently if silicone rubber is to be used the tubes must be engaged using a friction fit alone and of course such a fit is subject to disconnection and adds another risk factor to the use of the catheter. It is therefore most common to use PU extensions which are permanently bonded to the remainder of the catheter.

There are other problems associated with the use of clamps. The structure needed for the clamps is bulky and unwieldy. It has also been found that unless the clamps are aligned accurately before they are engaged, they can be disengaged by a minor impact and such disengagement is visually evident only by close scrutiny.

Accordingly it is an object of the present invention to provide vascular access catheters having a structure for opening and closing the flow through the catheter which is reliable, maintains patency regardless of the time during which the catheter is not in use, and which is compact and convenient both to store when not in use and to operate in use. It is also an object of the invention to provide structure which provides a reliable visual indication of whether or not the structure is open or closed to flow.

10 <u>DISCLOSURE OF THE INVENTION</u>

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The invention provides a catheter comprising an elongate main body including a pair of lumens and extending between proximal and distal ends and connection structure including a housing attached directly to said proximal end and defining a pair of passages forming continuations of the respective lumens, a pair of rotary valves including valve housings formed in said housing and having respective axes of rotation lying in a common plane and including barrels rotatable in said valve housings on actuation of the valves, and a ganged operator attached to the barrels between the barrels for actuating the valves.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a diagrammatic perspective view of a preferred embodiment of a catheter according to the invention and enlarged to better show the parts, the view including an operator shown in a closed position in full outline and in an open position in ghost outline:

Fig. 2 is a sectional view of the catheter on line 2-2 of Fig. 1 and showing in ghost outline how a housing would be flexed during assembly; Fig. 3 is a view similar to Fig. 2 with the operator in the open position;

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Fig. 4 is a front view of a second embodiment of catheter according to the invention with an operator in closed position;

Fig. 5 is a side view of the second embodiment with the operator shown in an open position, and also shown in ghost outline in the closed position; and

Fig. 6 is an exploded view of a two-part operator which could be used in the second embodiment.

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BEST MODES FOR CARRYING OUT THE INVENTION

Reference is made firstly to Fig. 1 which illustrates (to an enlarged scale) a catheter designated generally by the numeral 20 and consisting essentially of three main parts, namely elongate main body 22, a connection structure designated generally by the numeral 24, and a suture wing structure 26 which is rotatably mounted on the catheter where the main body 22 meets the connection structure 24. The main body is exemplary of different cross sections and in this case includes a pair of side-by-side lumens 28, 30 which are connected to passages 32, 34 starting in luer connectors 33, 35 and continuing through structure 24 as will be described more fully with reference to Fig. 2. For the moment it is sufficient to understand that these passages provide two different functions in most uses. The passage 32 connects to the lumen 28 which is an intake lumen terminating at side openings 36, and the passage 34 connects to a return lumen 30 which extends to the tip of the catheter ending at an end opening 38 and side openings 40. As a result, when the catheter is attached to equipment such as a dialysis machine, blood would be withdrawn via passage 32 and after treatment, returned to passage 34 so that within the vascular access, blood would flow

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through side openings 36 into the catheter and returned through end opening 38 and side openings 40.

During treatment and between treatments, it is necessary to close off these flows and then to re-establish them. It is clearly necessary to provide a visual indication of the status of the catheter, both in the open and in the closed positions. This visual indication should be as evident as possible so that even cursory examination of the catheter would reveal the status of the catheter. To this end, the catheter shown in Fig. 1 includes an operator 42 moveable angularly between the position shown in full outline where the passages are closed, and an open position indicated in ghost outline at 44. The operator is coupled to respective first and second valves 46, 48. The valves are set in a housing 50 which includes a main portion 52 and from that depends a pair of divergent valve housings 54, 56 containing the valves 46, 48. It will now be evident that the operator 42 controls both valves simultaneously and is therefore "ganged".

Reference is next made to Fig. 2 to more fully describe the connection structure designated generally by the numeral 24.

As seen in Fig. 2, the main portion 52 of the housing 50 is generally V-shaped in that it widens as it extends away from a direct connection to the proximal end of the main body 22. However the housing is substantially of constant thickness so that it presents a flat appearance. Also, the result is that the transverse cross-section of the housing increases as it widens so that it has maximum flexibility near the main body for reasons which will be explained.

The housing 50 defines a narrow slot 58 which extends axially of the catheter from between the respective valve housings 54, 56, terminating at a stress relieving opening 60. This slot

facilitates assembly as will be described.

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The valves 46, 48 include respective barrels 62, 64 which are sliding fits within corresponding openings 66, 68 formed in the housing. The axes of these openings lie respectfully at right angles to the associated passages 32, 34 and the barrels 62, 64 are attached at their adjacent ends to the operator 42. The barrels also define respective through holes 70, 72 which, when aligned with the passages 32, 34 by moving the operator into the ghost outline position shown in Fig. 1, provides through flow along the passages 32, 34. Of course in the position shown in Fig. 2, the operator is in a position where the barrels have closed the passages.

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Although the axes of the barrels lie in a common plane, they are angled relative to one another in order to put the barrels at right angles to the passages 32, 34. The amount of this misalignment is dependent upon the structure designed for the housing 50 and a different arrangement will be described with reference to Fig. 4. It will be appreciated that the material selected for the housing will be compatible with that of the main body as is common practice in the art. Also the grade of material will permit some flexing of the housing to facilitate assembly.

The respective barrels are located in the associated openings by end washers 74, 76 located in recesses in the valve housings and retained in position by respective enlargements 78, 80 on the ends of the barrels.

It should also be noted in Figs. 1 and 2 that the operator 42 is essentially two arms 82, 84 extending in parallel from the associated barrels and joined at a bale 86 at the outer extremity of the operator. There is therefore an inherent flexibility in the operator which is needed to accommodate the misalignment of the barrels as the operator is moved between open and closed positions.

Some of this flexibility is illustrated in Fig. 3 where the operator is in the open position and the through holes 70, 72 are in line with the associated passages 32, 34.

It will be evident from a review of Figs. 1 and 2 that the connection structure 24 is both compact and convenient both for 5 the patient and for an attendant operating the catheter. The housing is shaped to flex so that it is held down by a surgical dressing, the small misalignments between the housing and the main body will be accommodated. Further, there is a very clear indication when the catheter is open or closed because the operator 10 42 is of a significant dimension relative to the remainder of the catheter and the condition of the catheter will be evident from the observed position of the operator. As mentioned briefly previously the arrangement is such that the connection structure 24 is relatively flat when the operator is closed. In other words, the 15 accommodation of the valves is done by providing width in the structure 24 as opposed to depth measured at right angles to the plane containing the axes of the barrels 62, 64 (Fig. 2). In this context, the term "flat" is intended to indicate that this front to back depth extending between major surfaces of the structure has 20 been minimized in order to improve the convenience for the patient when the catheter is in place but not in use and not connected to dialysis or other equipment.

It is also to be noted that the catheter is reversible in the event that the catheter has to be rotated within the wing structure 25 26. The catheter can be turned and the operator 44 can be operated from the opposite side of that shown in Fig. 1. This is very important because the same visual indication is then apparent regardless of which is the front and which is the back of the catheter when viewed by an attendant. This is of particular value

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when using a catheter having lumens of the type shown in Fig. 1 where rotation is made necessary by the limitations of the side-by-side design. These limitations include the fact that the openings 36 must by design be on one side of the catheter and suction applied through the catheter can draw the side of the catheter into contact with a blood vessel. The remedy is then to rotate the catheter. This problem is less evident in coaxial catheters where the inlet openings are positioned about the entire periphery of the catheter. A main body of the coaxial type can of course be substituted for that shown in Fig. 1. The connections between the main body 22 and the connection structure 24 are well advanced in the art and therefore not described.

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It will be clear from Figs. 1 to 3 that when the operator 42 is moved between the open and closed positions, the misalignment of the axes of rotation of the valves 46, 48 will cause some change in shape of the operator as has been described with reference to Fig. 3. As a result the operator must be designed to flex readily so that minimal energy will be stored and the force to be applied to move the operator will also be minimized. To assist positive location, the arms 82, 84 have respective rounded projections 83, 85 (Fig. 2) which resiliently engage in corresponding depressions in the valve bodies. Exemplary depressions are seen at 87 in Fig. 1. Each projection can locate in a depression to locate the operator in the valve closed position, and two other depressions can be used for one of the two open positions as previously explained.

Although the catheter has been described with a single operator, it will be evident that with minor changes it will be possible to provide individual arms such as arms 82, 84 without the bale 86. It will still be convenient to operate both of the valves simultaneously by gripping both of the arms and moving them

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together but it is also possible to move the arms individually. The term "ganged" in the present context is intended to mean that the operator could be a single operator as shown in Fig. 2 or it could be two separate operators positioned to be operated simultaneously by simple movement of a finger or a thumb.

Reference is next made to Fig. 4 to show an alternative embodiment which is perhaps more desirable where more security for an operator is required. As seen in Fig. 4, a catheter designated generally by the numeral 100 has a main body 102 and a connection structure indicated generally by the numeral 104 attached directly to the main body. As usual, a wing structure 106 is included.

In the embodiments shown in Figs. 4 and 5, a housing 108 is generally V-shaped terminating at respective valve housings 110, 112 which are attached to one another after assembly by adhesive at a joint 114. The structure 104 defines passages 114, 116 which pass through valves 118 and 120 respectively and which terminate at luer connectors 122, 124.

The catheter includes an operator 126 which is attached to aligned barrels 128, 30 passing through the respective valve

housings 110, 112 and defining through holes 132, 134. As shown, the operator is in the closed position, when it is moved from the closed position shown in Fig. 4 to the an open position (Fig. 5) the through holes would be in alignment with the passages 114, 116.

The structure shown in Figs. 4 and 5 would be assembled by first separating the valve housings 110, 112 using the flexibility of the V-shaped main portion of the housing 108. The deflection is sufficient to permit the operator 126 and associated barrels 128, 130 to be engaged with the valve housings and the valve housings are then brought together in alignment and the joint 114 is closed. The assembly would be completed by applying an adhesive or bonding

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agent to the joint before closing it. An alternative of course would be to make a mechanical connection.

Once assembled, the structure shown in Figs. 4 and 5 has the advantages of being very compact, convenient to use, and it provides some protection for the operator 126 against accidental opening. Once the operator is in the position shown in Fig. 4, it is essentially confined within an elongate opening 136 and, as seen in Fig. 5, the extent of the operator is such that it is within the confines of the depth or thickness of the connection structure 104 when it is in the closed position. On the other hand, the extent of the operator 126 is such that when it is in the open position as shown in full outline in Fig. 5, there is a very ready visual indication of the status of the catheter.

The opening 136 also has another purpose. The transverse cross-section of the housing is minimized by the presence of the opening to enhance the flexibility near the junction with the main body.

As described previously with reference to Figs. 1 to 3, the convenience for the user of a catheter of this type is due to the compactness and flatness of the connection structure. This is emphasized in the structure shown in Figs. 4 and 5 due to the fact that the operator is contained within the connection structure as opposed to extending beyond it as seen in Fig. 1. Consequently the Fig. 4 structure may well be preferred in some circumstances.

Another advantage of the Fig. 4 structure is the fact that although the barrels 128, 130 of the valve lie in the same plane, they are also coaxial. This is an advantage in that the operator 126 can be a simple structure as opposed to the more complicated structure shown in Fig. 1. It will also be evident that it would be a simple matter to modify the operator 126 into two parts. As seen in Fig.

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6, an operator 138 has first and second parts 140, 142 having respective barrels 144, 146 and arms 148, 150. The arm 150 carries a central small projection 152 located on the axis of rotation to separate the arms and minimize friction between them. Although the operator 138 is ganged to be operated by one finger, the individual parts 140, 142 allow the valves to be moved independently.

These and other structures are within the scope of the invention as claimed.

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INDUSTRIAL APPLICABILITY

Catheters according to the invention are used in essentially the same way as prior art catheters. However the invention provides rotary valves which the user can operate to open and close passages in the catheter. The valves give an immediate visual indication of the status of the catheter. Also, the housing containing the valves is attached directly to the main body of the catheter and is compact for convenient storage when not in use. It is shaped to widen in a direction away from the main body so that when the housing is taped in place using surgical dressing, there will be some deflection mainly where the main body and housing meet so that the user can tape the catheter to the patient conveniently. When opening and closing the valves, a ganged operator allows both valves to be moved contemporaneously or, if preferred, individually.

INDEX OF REFERENCE SIGNS

	20	Catheter	22	Main body
	24	Connection structure	26	Wing structure
	28	Lumen	30	Lumen
5	32	Passage	33	Luer connector
	34	Passage	35	Luer connector
	36	Side opening	38	End Opening
	40	Side opening	42	Operator
	44	Open position	46	Rotary valve
10	48	Rotary valve	50	Housing
	52	Main portion	54	Valve housing
	56	Valve housing	58	Slot
	60	Opening	62	Barrel
	64	Barrel	66	Opening
15	68	Opening	70	Through hole
	72	Through hole	74	Washer ·
	76	Washer	78	Enlargement
	80	Enlargement	82	Arm
	84	Arm	86	Bale
20	100	Catheter	102	Main body
	104	Connecting structure	106	Wing structure
	108	Housing	110	Valve housing
	112	Valve housing	114	Passage
	116	Passage	118	Valve
25	120	Valve	122	Luer connector
	124	Luer connector	126	Operator
	128	Barrel	130	Barrel
	132	Through hole	134	Through hole
	136	Elongate opening	138	Operator
30	140	Part	142	Part

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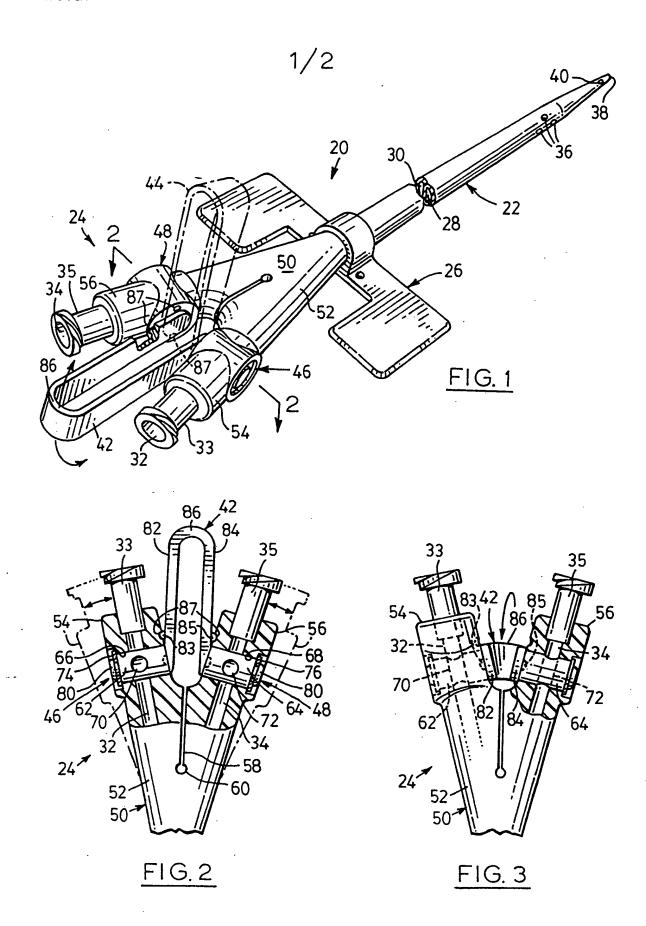
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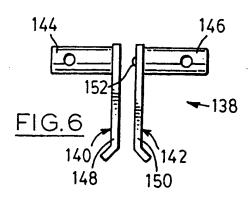
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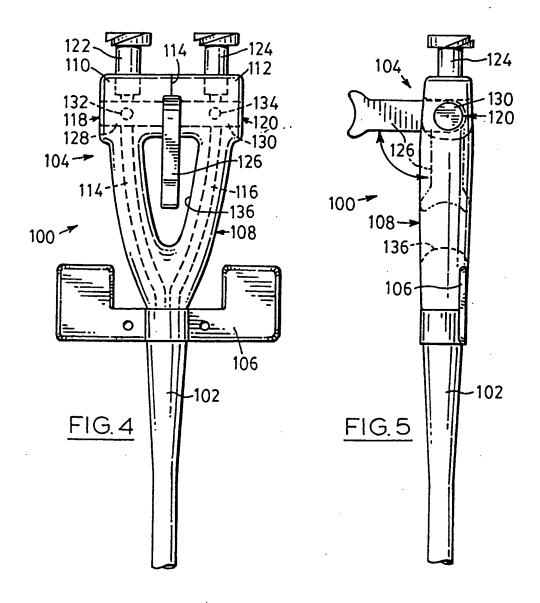
CLAIMS

- 1. A catheter (20, 100) comprising:
 an elongate main body (22, 102) including a pair of
 lumens (28, 30) and extending between proximal and distal ends; and
 connection structure (24, 104) including a housing (50,
 108) coupled to said proximal end and defining a pair of passages
 (32, 34) forming continuations of the respective lumens, a pair of
 rotary valves (46, 48; 118, 120) including valve housings (54, 56; 110,
 112) formed in said housing and rotatable in said valve housings on
 10 actuation of the valves to open and close the passages as required,
 the housing widening as it extends from the main body thereby
 providing more flexibility in the housing near the main body.
- 2. A catheter as claimed in claim 1 in which the valves
 15 include respective barrels (62, 64; 128, 130) rotatable about respective axes.
- 3. A catheter as claimed in claim 2 in which the axes lie in a common plane and the valves include a ganged operator (42, 126)
 20 moveable regularly to open and close the valves.
 - 4. A catheter as claimed in claim 3 in which the axes are substantially coaxial.
- 25 5. A catheter as claimed in claim 3 in which the operator is in two parts (140, 142) operable together or independently.
 - 6. A catheter as claimed in claim 3 in which the ganged operator includes a pair of arms (82, 84) extending from the respective barrels and ending in a bale (86).

- 7. A catheter as claimed in claim 4 in which the operator is in two parts (140, 142) located adjacent one another for operation together or independently.
- 5 8. A catheter as claimed in claim 1 in which the housing defines a through opening (136) between the main body and the valves and between the passages.
- A catheter as claimed in claim 8 in which the valves
 include a ganged operator (42, 126) moveable angularly to open and close the valves and in which the operator is contained in the through opening when the valves are closed.
- 10. a catheter as claimed in claim 1 in which the valve15 housings are attached to one another at a joint in the housing after assembly.







SUBSTITUTE SHEET (RULE 26)

Intern al Application No PCT/CA 94/00339

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61M25/00 A61M5/ A61M5/158 According to International Patent Classification (IPC) or to both national classification and IPC Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61M Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. Category * 1,7 WO, A, 88 10128 (HOWES) 29 December see page 8, paragraph 3 - page 9, paragraph 5; figure 7 1,2,5,7, EP, A, O 299 158 (MANSFIELD) 18 January A see column 10, line 15 - line 29; figures 3,4,7 1,2 WO,A,94 07556 (RÜSCH) 14 April 1994 Α see abstract; figures 1,2 US,A,4 959 058 (MICHELSON) 25 September 1,7 A 1990 see column 2, line 62 - column 3, line 21; figure 1 -/--Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance invention earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docudocument referring to an oral disclosure, use, exhibition or ments, such combination being obvious to a person skilled document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of mailing of the international search report Date of the actual completion of the international search 2 3, 02, 95 9 February 1995 Authorized officer Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

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INTERNATIONAL SEARCH REPORT

Inten al Application No
PCT/CA 94/00339

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C.(Continua	tion) DOCUMENTS CONSIDERED TO BE RELEVANT			
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E	US,A,5 324 274 (MARTIN) 28 June 1994		1,2,5,8, 10	
	see the whole document			
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